Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D2210494	01/31/2022
Name of Provider or Supplier	**Street Address, City, State**	
Foot Health Center, Llc	3106 Houma Blvd, Metairie, LA	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	An Initial survey was performed on January 31, 2022 at Foot Health Center, LLC, CLIA ID # 19D2210494. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of the laboratory's personnel policy and interview with personnel, the laboratory failed to have complete policies for competency assessment of the General Supervisor. Findings: 1. Review of the laboratory's "Personnel" policy revealed the laboratory did not define the frequency of performance of competency assessments for the duties of the General Supervisor. 2. In interview on January 31, 2022 at 10:34 am, the Compliance personnel confirmed the laboratory's written personnel policy did not include the frequency of performance of competency assessments for the duties of the General Supervisor.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by:

	Based on observation by surveyor and interview with surveyor, the laboratory failed to ensure reagents did not exceed their expiration dates. Findings: 1. Observation by surveyor during laboratory tour on January 31, 2022 at 9:59 am revealed the following expired item: Applied Biosystems Mag Max Viral/Pathogen Binding Solution, Lot 2011142, Expiration date: 2021-12-02, Quantity: one (1) bottle, half (1/2) full 2. In interview on January 31, 2022 at 9:59 am, the General Supervisor confirmed the identified item was expired. The General Supervisor stated she does not use the item and forgot it was in the cabinet.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on observation by surveyor, review of the laboratory's establishment of performance specifications studies, test menu, and interview with personnel, the laboratory failed to perform complete precision studies for microbiology (bacteriology and mycology) testing. Findings: 1. Observation by surveyor during the laboratory tour on January 31, 2022 at 9:59 am revealed the laboratory utilizes the QuantStudio 12K Flex instrument for bacteriology and mycology testing of wound and nail samples. 2. Review of the laboratory's "Summary Report for Wound Microbiota and Antibiotic Resistance Marker Assays on the Applied Biosystems QuantStudio 12 K Flex Taqman Array Card (TAC) Platform" under "Reproducibility and Precision" section revealed "Reproducibility was analyzed by examining the 'present' or 'absent' classification for each sample over the three-day period. Precision was evaluated by calculating Crt standard deviation of replicates within single cards and across the three-day period." 3. Review of the laboratory's "Summary Report for 'Nail Fungus' Microbiota TaqMan on the Applied Biosystems QuantStudio 12 K Flex Taqman Array Card (TAC) Platform" under "Reproducibility and Precision" section revealed "Reproducibility was analyzed by examining the 'present' or 'absent' classification for each sample over the validation period." 4. Review of the laboratory's establishment of performance (validation) studies including raw data revealed the laboratory ran three (3) runs on February 14, 2021, not over a three-day period. The laboratory's establishment of performance studies did not include day-to-day studies. 5. In interview on January 31, 2022 at 11:31 am, the Compliance personnel confirmed the laboratory's precision studies did not include day-to-day studies. 6. Review of the laboratory's test menu revealed the laboratory performs 1,082,400 microbiology tests annually. II. Based on observation by surveyor, review of the laboratory's establishment of performance specifications studies, manufacturer instructions, test menu, and interview with personnel, the laboratory failed to establish specimen stability for microbiology (bacteriology and mycology) testing. Findings: 1. Observation by surveyor during the laboratory tour on January 31, 2022 at 9:59 am

	revealed the laboratory utilizes the QuantStudio 12K Flex instrument for bacteriology and mycology testing of wound and nail samples. 2. Review of the BD Liquid Amies Elution Swab (ESwab) instructions revealed the following instructions under "Specimen Collection, Storage, and Transportation" section: "To maintain optimum viability, transport specimens collected using BD ESwab directly to the laboratory, preferably within 2 hours of collection. If immediate delivery or processing is delayed, then specimens should be refrigerated 4-8 degrees C or stored at room temperature (20-25 degrees C) and processed within 48 hours except for Neisseria gonorrhoeae cultures should be processed with 24 ours." 3. Review of the laboratory's performance specification studies summaries for wound and nail specimens revealed the following under "Transport Media" section : "all samples in this validation were processed in COPAN eswab matrix to ensure no matrix effects are present in this assay. Results from the validation show no eSwab matrix effects were detected in the assay. Furthermore, stability of DNA is the COPAN eSwab system is justified by scientific literature performing DNA stability studies on DNA in the COPAN eSwab system. Data from these studies show DNA stability is > 95% over 28 days at room temperature in the eSwab matrix. Furthermore, DNA stability at -20 degrees C has been consistently proven over last 30 years of molecular research with stability demonstrated up to 3 years when frozen. Samples can be frozen and thawed up to two times before any detectable loss of DNA is observed. Therefore, when considering the aforementioned evidence. Samples are considered stable for 28 days from collection for DNA analysis at room temperature and up to 3 years when frozen at -20 degrees C. Additionally, samples that have been frozen are considered fully viable for molecular testing as long as they are not freeze thawed more than two times." 4. The laboratory cited the following articles: "Long -Term Stability and Integrity of Plasmid-Based DNA Data Storage" and "Aerobic bacteria as Escherichia coli can survive in Eswab TM Medium after a 3 month freezing at -80 degrees C but not after multiple thawing." 5. In interview on January 31, 2022 at 10:05 am, the General Supervisor stated all samples are stored frozen. The General Supervisor stated samples can be frozen up to thirty (30) days. The General Supervisor did not state the number of freeze thaw cycles the laboratory allows. The General Supervisor stated wound samples are run at least weekly and nail samples she tries to at least have seven (7) samples before running. 6. Review of the laboratory's performance specification studies revealed the laboratory did not include stability studies for detection of the bacteria and fungi the laboratory reports in frozen samples. 7. In interview on January 31, 2022 at 1:21 pm, the Compliance personnel stated the laboratory did not perform stability studies for frozen samples.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of patient final test reports, test menu, and interview with personnel,

	the laboratory failed to include on the patient final test report for non-FDA approved test a disclaimer stating "The performance characteristics of this test were determined by Foot Health Center, LLC. It has not been cleared or approved by the U.S. Food and Drug Administration" for five (5) of five (5) reports reviewed. Findings: 1. Review of random selection of the following five (5) patient reports revealed the laboratory did not include the above disclaimer: Patient 123045 Nail 007 Patient 030541 Nail 004 Patient 100947 WND 005 Patient 021043 Nail 005 Patient 092777 WND 005 2. In interview on January 31, 2022 at 12:33 pm, the Compliance personnel confirmed the laboratory did not include the above disclaimer on patient reports. 3. Review of the laboratory's test menu revealed the laboratory performs 1,082,400 microbiology tests annually.
D6087	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(iii) The laboratory director must ensure that laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on observation by surveyor and interview with personnel, the Laboratory Director failed to ensure laboratory personnel performed test methods as required. Refer to D5417.
D6098	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(8) The laboratory director must ensure that reports of test results include pertinent information required for interpretation. This STANDARD is not met as evidenced by: Based on review of patient final reports, test menu, and interview with personnel, the laboratory failed to ensure patient final reports included required information. Refer to D5805.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure policies and procedures for assessing personnel competency were maintained. Findings: 1. The laboratory failed to have complete policies for

	competency assessment of the General Supervisor. Refer to D5209. 2. The Technical Supervisor failed to perform the semi-annual competency assessment for one (1) of two (2) testing personnel reviewed. Refer to D6127.
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of the laboratory's CMS 209 form, personnel records, and interview with personnel, the Technical Supervisor failed to perform the semi-annual competency assessment for one (1) of two (2) testing personnel reviewed. Findings: 1. Review of the laboratory's CMS 209 (Laboratory Personnel Report) form revealed the Laboratory Director also serves as the Technical Supervisor. 2. Review of personnel records for the General Supervisor, who also serves as Testing Personnel, revealed the semi-annual competency assessment was performed on October 11, 2021 by the laboratory's Compliance personnel, not the Technical Supervisor. 3. In interview on January 31, 2022 at 10:34 am, the Compliance personnel confirmed she performed the semi-annual competency asssessment for the General Supervisor, for ther testing personnel duties.